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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,588	07/08/2003	Joe S. Wilkins JR.	WRC/8B	8936

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EXAMINER

KRASS, FREDERICK F

ART UNIT PAPER NUMBER

1614

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,588

Applicant(s)

WILKINS, JOE S.

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>A and B</u> . | 6) <input type="checkbox"/> Other: ____. |

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6, 10-12, 14, 15, 17, 18, 19, and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The percent values recited throughout the rejected claims are indefinite insofar as the basis for their calculations are not set forth, e.g., percent by weight, by volume, by mole, etc. See Honeywell Intl., Inc. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the particular method of measurement is recited.)

2) The term "about" as recited throughout the claims, e.g. "about" 15 percent in claim 3, is viewed as being indefinite in this particular fact situation.

Normally, the term "about" is not considered indefinite. In certain specific factual situations in which close prior art exists, however, the courts have recognized that sufficient ambiguity may arise to render the term indefinite. See specifically Amgen v. Chugai, 927 F.2d 1200 (Fed. Cir. 1991), where the court found that the recitation of a specific activity of "about" 160,000 gave no hint as to which value between the prior art value of 128,620 and 160,000 constituted infringement and hence is indefinite. As noted at page 1218 of the decision, the holding was further supported by the fact that "nothing in the specification, prosecution history, or prior art provides any indication as to what range of specific activity is covered by the term". That is the case here, because prior art having a specified upper limit of 10 percent limonene exists (as applied infra), and the instant specification provides no hint as to how far the term

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"about" extends, e.g. in claim 3 it is unclear how far below 15 percent one can go and still infringe the term "about" 15.

3) Claim 18, first line, there is no antecedent basis for "said bacteria" in claim 1.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-3, 9, 11, 12, 16, 18, 20, 31 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Wahlstam (WO 80/02371).

The prior art discloses toothpastes for plaque removal (and thus the inhibition of plaque forming bacteria as required by instant claims 16 and 18) comprising d-limonene in an amount up to 10 percent by weight; up to 5 percent by weight thickener; up to 30 percent by weight moisture retaining agent (i.e., humectant/polyol, e.g., glycerine, propylene glycol, sorbitol and other polyalcohols: see p. 7)); and other conventional additives such as abrasives (p. 2, lines 12-27), nonionic surfactants (p. 4, line 29 et seq), and thickeners/binders (see p. 7).

Although the preferred amount of limonene in the prior art is up to 10 percent, this is nevertheless viewed as anticipating the instant lower limit of "about 15 percent" as recited by instant claims 3, 12 and 23. This is so because the term "about" is not defined by the instant specification and is thus indefinite (see subsection "2)" of the "Indefiniteness" section supra). Absent a clear definition of the term, the

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examiner is justified in interpreting it as broadly as is reasonable, and certainly a variation on the order of 5 percent or somewhat less than 5 percent (10 of the prior art versus "about" 15 of the instant claims) would seem to be fairly within the scope of the term "about", given that the claimed range of limonene varies much more widely than that (from 10 to 25 percent).

2) Claims 1, 9, 13, 16, 18 and 20 rejected under 35 U.S.C. 102(b) as being anticipated by Delli Santi et al (USP 6,235,267).

The prior art discloses oral rinses and dentifrices comprising water, up to 5 percent by weight citrus flavor or a citrus flavor ingredient, 0.1 to 70 percent of a humectant polyol such as glycerine, sorbitol, propylene glycol, xylitol, or mixtures thereof; and up to 10 percent by weight surfactants (also polyols) for the treatment of plaque and gingivitis (col. 2, lines 12-47). The preferred citrus flavor ingredient is d-limonene (col. 3, lines 18-20). Preferred toothpastes contain up to 60 percent by weight abrasive (col. 4, lines 26-38), as well as binders (col. 5, lines 13-23).

3) Claims 1-3, 7, 9, 11-13, 16, 18, 20, 21 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Wolnerman (WO 01/70184).

The prior art discloses the treatment of diseases of the oral cavity, e.g., plaque, gingivitis and periodontal disease, with oral care compositions comprising d-limonene, including mouthwashes and toothpastes (p. 4, first two paragraphs). The preferred amount of limonene ranges up to 10 percent by weight (p. 5, eighth full paragraph). Mixtures of magnesium and calcium salts are also included in the form of "Carnalite" (p. 5, third and fourth full paragraphs). Preferred toothpastes comprise 10 to 50 percent abrasive, 0.5 to 10 percent surfactants (which are also polyols), 10 to 55 percent humectant (a term from which anyone of ordinary skill in the art would envisage glycerin), and 2 to 45 percent water; preferred mouthwashes comprise 45 to 95 percent water, up to 50 percent humecant (polyol), and 0.01 to 7 percent surfactant (p. 8, last two full paragraphs). The toothpastes also include 0.1 to 5 percent by weight thickening agent (i.e., binder – see penultimate line p. 7): note that xanthan gum is used in working example 2a at p. 18, and carboxymethylcellulose in working example 2d at p. 20. Besides the implicit

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disclosure of polyols as "humecants", the prior art also explicitly discloses polyol sweeteners, e.g., sorbitol and xylitol at the bottom of p. 11.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 3, 12, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolnerman (WO 01/70184).

Note that, for the purposes of this ground of rejection only and purely arguendo, the presumption will be made that "about 15" is not anticipated by "10".

Wolnerman is discussed in subsection "3)" of the "Anticipation" rejection supra, and differs from the instant claims insofar as limonene levels higher than 10 percent are not specifically disclosed. The prior art does, however, provide the following teaching at the bottom of p. 6:

'Safe and effective amount' as used herein is meant to denote an amount of monoterpene with three unsaturation derivatives, high enough to significantly (positively) modify the condition to be treated, but low enough to avoid serious side effects (at a reasonable benefit/risk ratio), within the scope of sound medical/dental judgment. The safe and effective amount of monoterpenes, will vary the particular condition.

Accordingly, it would have been obvious to have tested and used amounts higher than 10 percent based on this teaching. Indeed, given these facts, it would appear that Applicant has done nothing more than routinely test to find the upper limit of the safe and effective amount which can be used in oral care compositions; no evidence of unexpected results has been shown.

This position is entirely consistent with and supported by established precedent as well: see In re Aller 105 USPQ 233, 235 (CCPA 1955); and In re Boesch, 205 USPQ 215 (CCPA 1980). See also In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003). (That court reaffirming the previous Aller and Boesch decisions, stating at page 1330 that experimentation to determine workable ranges and optimal values is a "normal desire" of scientists which renders such experimentation generally obvious).

2) Claims 4-6, 10, 17, 19, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wahlstam (WO 80/02371) in view of Kruger, Jr. et al (USP 5,220,105).

The primary reference is discussed in subsection "1)" of the "Anticipation" section supra, and differs from the instant claims insofar as it does not specifically disclose d-limonene having a purity of 98.5 percent or greater. The preferred limonene is derived from citrus peels (p. 4, lines 25-28).

The secondary reference discloses a method for making purified d-limonene, teaching that the method is necessary because limonene derived from citrus peels tends to have an undesirable smoky odor due to impurities (see col. 1 in its entirety, and the first two lines of col. 2). The secondary reference differs from the instant claims insofar as it does not disclose oral care compositions.

It would have been obvious to have used purified limonene in the oral care compositions of the primary reference, motivated by the desire to avoid the smoky odor present in limonene derived from citrus peels, as taught by the secondary reference.

3) Claims 4, 10, 14, 15, 17, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delli Santi et al (USP 6,235,267) in view of Kruger, Jr. et al (USP 5,220,105).

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The primary reference is discussed in subsection "2)" of the "Anticipation" section supra, and differs from the instant claims insofar as it does not specifically disclose d-limonene having a purity of 98.5 percent or greater. (The preferred limonene is a "citrus flavor component", i.e., is derived from citrus, and has a purity of 90-95 percent (col. 3, lines 18-20)).

The secondary reference discloses a method for making purified d-limonene, teaching that the method is necessary because limonene derived from citrus peels tends to have an undesirable smoky odor due to impurities (see col. 1 in its entirety, and the first two lines of col. 2). The secondary reference differs from the instant claims insofar as it does not disclose oral care compositions.

It would have been obvious to have used purified limonene in the oral care compositions of the primary reference, motivated by the desire to avoid the smoky odor present in limonene derived from citrus peels, as taught by the secondary reference.

4) Claims 4-6, 8, 10, 14, 15, 17, 19, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolnerman (WO 01/70184) in view of Kruger, Jr. et al (USP 5,220,105).

The primary reference is discussed in subsection "3)" of the "Anticipation" section supra, and differs from the instant claims insofar as it does not specifically disclose d-limonene having a purity of 98.5 percent or greater. Instead, the limonene is preferably from a natural source, i.e., essential oils of citrus (see the bottom of p. 4 and the top of p. 5); see also pp. 16 and 17, where the highest level of limonene specified in the working examples is 92 percent.

The secondary reference discloses a method for making purified d-limonene, teaching that the method is necessary because limonene derived from citrus peels tends to have an undesirable smoky odor due to impurities (see col. 1 in its entirety, and the first two lines of col. 2). The secondary reference differs from the instant claims insofar as it does not disclose oral care compositions.

It would have been obvious to have used purified limonene in the oral care compositions of the primary reference, motivated by the desire to avoid the smoky odor present in limonene derived from citrus peels, as taught by the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

